

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ACTELION PHARMACEUTICALS
LTD. and ACTELION CLINICAL
RESEARCH, INC.,

Plaintiffs/Counterclaim-Defendants,

v.

APOTEX INC., APOTEX CORP.,
ROXANNE LABORATORIES, INC.,
and ACTAVIS ELIZABETH LLC,

Defendants/Counterclaim-Plaintiffs.

Civil Action No. 1:12-cv-05743-NLH-AMD

Honorable Noel L. Hillman

ECF Filing

**DEFENDANTS/COUNTERPLAINTIFFS' JOINT MEMORANDUM IN OPPOSITION
TO PLAINTIFFS/COUNTERDEFENDANTS' MOTION TO STAY DISCOVERY**

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TABLE OF CONTENTS

	<u>Page</u>
TABLE OF AUTHORITIES	iii
INTRODUCTION	1
BACKGROUND	2
ARGUMENT.....	3
I. ACTELION’S FILING OF A DISPOSITIVE MOTION DOES NOT CONSTITUTE GOOD CAUSE FOR STAYING DISCOVERY.	4
II. ACTELION HAS NOT DEMONSTRATED THAT DISCOVERY IN THIS CASE WOULD BE UNDULY BURDENSOME OR EXPENSIVE.	7
III. A STAY OF DISCOVERY WOULD PREJUDICE THE PUBLIC AND DEFENDANTS/COUNTERPLAINTIFFS BY PROLONGING THIS LITIGATION AND FURTHER DELAYING DEFENDANTS/COUNTERPLAINTIFFS’ ABILITY TO BRING GENERIC VERSIONS OF TRACLEER AND ZAVESCA TO MARKET. ..	9
CONCLUSION.....	10

TABLE OF AUTHORITIES**Page(s)****CASES**

<i>Ariano Castro, M.D., P.A. v. Sanofi Pasteur Inc.</i> , No. 2:11-cv-07178 (D.N.J. 2011).....	5, 6
<i>Bell Atlantic Corp. v. Twombly</i> , 550 U.S. 544 (2007)	7
<i>Cipollone v. Liggett Grp., Inc.</i> , 785 F.2d 1108 (3d Cir. 1986)	7
<i>Coca-Cola Bottling Co. v. Grol</i> , Civ. A. No. 92-7061, 1993 WL 13139559 (E.D. Pa. Mar. 8, 1993)	4
<i>Coyle v. Hornell Brewing Co.</i> , Civil No. 08-2797 (JBS/JS), 2009 WL 1652399 (D.N.J. June 9, 2009)	3, 4
<i>Forrest v. Corzine</i> , 757 F. Supp. 2d 473 (D.N.J. 2010).....	3, 4, 9
<i>Gerald Chamales Corp. v. Oki Data Ams., Inc.</i> , 247 F.R.D. 453 (D.N.J. 2007)	<i>passim</i>
<i>Harlow v. Fitzgerald</i> , 457 U.S. 800 (1982)	5
<i>In re Lipitor Antitrust Litig.</i> , No. 3:12-cv-2389 (D.N.J. 2012).....	5
<i>In re Plastics Additives Antitrust Litig.</i> , No. Civ. A. 03-2038, 2004 WL 2743591 (E.D. Pa. Nov. 29, 2004)	3, 9
<i>Landis v. N. Am. Co.</i> , 299 U.S. 248 (1936)	4
<i>Lannett Company, Inc. v. Celgene Corp.</i> , No. 2:08-cv-03920 (E.D. Pa. 2008).....	7
<i>Mann v. Brenner</i> , 375 F. App'x 232 (3d Cir. 2010).....	5
<i>Pearson v. Miller</i> , 211 F.3d 57 (3d Cir. 2000)	4

<i>United States Catholic Conf. v. Abortion Rights Mobilization, Inc.</i> , 87 U.S. 72 (1988)	5
<i>Victor v. Huber</i> , Civil No. 3:12-CV-282, 2012 WL 2564841 (M.D. Pa. July 2, 2012)	5
<i>Weisman v. Mediq, Inc.</i> , Civ. A. No. 95-1831, 1995 WL 273678 (E.D. Pa. May 3, 1995)	6
<i>Worldcom Techs., Inc. v. Intelnet Int’l, Inc.</i> , No. Civ.A. 00-2284, 2002 WL 1971256 (E.D. Pa. Aug. 22, 2002)	<i>passim</i>

RULES

Fed. R. Civ. P. 26(c)	2, 3-4
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OTHER AUTHORITIES

Gideon Mark, <i>Federal Discovery Stays</i> , 45 U. Mich. J.L. Reform 405 (Winter 2012)	5
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INTRODUCTION

Defendants/Counterplaintiffs Apotex Inc., Apotex Corp. (collectively, “Apotex”), Roxane Laboratories, Inc. (“Roxane”), and Actavis Elizabeth LLC (“Actavis”) respectfully submit this joint opposition to Plaintiffs/Counterdefendants Actelion Pharmaceuticals Ltd.’s and Actelion Clinical Research, Inc.’s (collectively, “Actelion”) Motion to Stay Discovery. Actelion has not satisfied, or indeed even attempted to satisfy, its burden to demonstrate the requisite “good cause” for a discovery stay under Federal Rule of Civil Procedure 26(c) for at least three reasons. First, although Actelion relies on the fact that it has filed a potentially dispositive motion, it is well established that such a filing does *not* constitute good cause for a discovery stay. This is particularly true here, where Actelion has not even argued that its dispositive motion is likely to be granted.

Second, Actelion has not demonstrated that the phased discovery proposed by Defendants/Counterplaintiffs would be unduly burdensome or expensive. Instead, Actelion contends only that discovery in antitrust cases “can be extremely expensive” without pointing to any specifics in this case. Actelion Br. 2. This is insufficient to demonstrate good cause.

Third and finally, a discovery stay would prejudice the public and Defendants/Counterplaintiffs by prolonging this litigation and further delaying the approval and sale of generic drugs that would compete with Actelion’s Tracleer and Zavesca. During an additional period of delay, Actelion would continue to reap monopolist’s profits; patients would continue to pay artificially high prices for Tracleer and Zavesca; and Defendants/Counterplaintiffs would continue to forego profits on generic versions of those drugs. Accordingly, this Court should deny Actelion’s Motion to Stay Discovery, and discovery should commence immediately.

BACKGROUND

Defendants/Counterplaintiffs are generic drug manufacturers that have been prevented by Actelion from purchasing samples of Actelion's brand-name drug Tracleer. Actelion also has prevented Roxane from purchasing samples of Actelion's brand-name drug Zavesca. Defendants/Counterplaintiffs need these samples to conduct bioequivalence studies of their generic Tracleer and Zavesca products. The results of these studies must be included in the Abbreviated New Drug Applications ("ANDAs") that Defendants/Counterplaintiffs will submit to the United States Food and Drug Administration ("FDA") for approval of their generic products. Defendants/Counterplaintiffs cannot market their generic products until FDA has approved their ANDAs. By refusing to sell samples (and closing the distribution channels completely) to Defendants/Counterplaintiffs for bioequivalence testing, Actelion has prevented Defendants/Counterplaintiffs from filing their ANDAs and, by doing so, is thwarting generic drug competition for these two products.

This case is extraordinarily important to the future of the pharmaceutical industry in this country. If brand-name drug manufacturers like Actelion can refuse to sell samples to generic manufacturers and preclude all other distributors from doing so, then the framework for expediting the development and approval of generic drugs that Congress constructed will be severely undermined, and approval of new generic drugs, which are substantially cheaper than their brand-name equivalents, will slow to a crawl. A speedy resolution to this case is very important to Defendants/Counterplaintiffs, whose efforts to develop and market generic alternatives to Actelion's products have already been delayed for months or, in some cases, years. If the pending Motion to Stay Discovery is successful, then Actelion will have bought itself additional months of delay even if its dispositive motion fails.

As Actelion knows from the parties' meet-and-confer and Defendants/Counterplaintiffs' proposed discovery plan as set forth in the Joint Pre-Conference Report, Defendants/Counterplaintiffs are amenable to conducting discovery in phases to minimize the costs of discovery at the outset. Under Defendants/Counterplaintiffs' proposed plan, discovery would be conducted in three phases, with each phase lasting three-to-four months. Ex. A, Joint Pre-Conference Report at Question No. 8(b). Phase I would consist of written discovery and the parties' exchange of a defined list of "core" documents; Phase II would consist of full-blown electronic discovery and depositions; and Phase III would consist of expert discovery. *Id.* In addition, Defendants/Counterplaintiffs have stated they are willing to bifurcate liability and damages discovery. *Id.* Notably, Actelion has rejected this proposed compromise and refused to offer any alternative solutions, insisting instead on a complete stay of discovery until such time that its dispositive motion is decided.

ARGUMENT

A discovery stay is an "extraordinary remedy" that is "not favored." *Forrest v. Corzine*, 757 F. Supp. 2d 473, 476 (D.N.J. 2010) (citations omitted); *Coyle v. Hornell Brewing Co.*, Civil No. 08-2797 (JBS/JS), 2009 WL 1652399, at *3 (D.N.J. June 9, 2009) (citations omitted); *In re Plastics Additives Antitrust Litig.*, No. Civ. A. 03-2038, 2004 WL 2743591, at *5 (E.D. Pa. Nov. 29, 2004) (citation omitted). This is "because when discovery is delayed or prolonged[,] it can create case management problems which impede the court's responsibility to expedite discovery and cause unnecessary litigation expenses and problems." *Coyle*, 2009 WL 1652399, at *3 (quoting *Worldcom Techs., Inc. v. Intelnet Int'l, Inc.*, No. Civ.A. 00-2284, 2002 WL 1971256, at *6 (E.D. Pa. Aug. 22, 2002)).

A discovery stay is appropriate only upon a showing of "good cause" to "protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense." Fed. R.

Civ. P. 26(c); *Coyle*, 2009 WL 1652399, at *3. “Good cause” requires a showing of a “particular need for protection,”” *Worldcom*, 2002 WL 1971256, at *6 (quoting *Pearson v. Miller*, 211 F.3d 57, 72 (3d Cir. 2000)), meaning that the party seeking a stay “must make out a clear case of hardship or inequity in being required to go forward” with discovery. *Forrest*, 757 F. Supp. 2d at 478 (quoting *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936)); *Coyle*, 2009 WL 1652399, at *3 (same) (citation omitted). Actelion has not even acknowledged the applicable “good cause” standard, let alone attempted to satisfy it. For the reasons discussed below, Actelion’s general, unsupported statements do not come close to satisfying its burden, and the Court should deny its Motion to Stay Discovery.

I. ACTELION’S FILING OF A DISPOSITIVE MOTION DOES NOT CONSTITUTE GOOD CAUSE FOR STAYING DISCOVERY.

Actelion contends that “this is a model case for a stay” because it has filed a potentially dispositive motion that “seeks a determination of the law based on undisputed facts.” Actelion Br. 2. This argument is wrong in two regards, as Actelion is neither correct on the law nor in stating that the relevant facts are undisputed. There is “no requirement that discovery must be stayed pending a decision” on a dispositive motion. *Gerald Chamales Corp. v. Oki Data Ams., Inc.*, 247 F.R.D. 453, 454 (D.N.J. 2007); *see also Coca-Cola Bottling Co. v. Grol*, Civ. A. No. 92-7061, 1993 WL 13139559, at *2 (E.D. Pa. Mar. 8, 1993) (“Had the drafters of the Federal Rules of Civil Procedure wanted an automatic stay of discovery pending a motion to dismiss[,] they could have so provided.”) (citations omitted). Indeed, “[i]t is well settled that the mere filing of a dispositive motion does not constitute ‘good cause’ for the issuance of a discovery stay.” *Coyle*, 2009 WL 1652399, at *3 (rejecting a motion to stay discovery pending a ruling on the defendants’ motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) (citing *Gerald Chamales Corp.*, 247 F.R.D. at 454 (denying a motion to stay discovery pending a resolution of

the defendants' summary judgment motion)).¹ This principle applies with full force to antitrust cases, as motions to stay discovery pending a ruling on a motion to dismiss recently were rejected in two antitrust cases pending in this District. *See* Ex. B, Order, *In re Lipitor Antitrust Litig.*, No. 3:12-cv-2389, Dkt. No. 197 (D.N.J. July 18, 2012); Ex. C., Order, *Ariano Castro, M.D., P.A. v. Sanofi Pasteur Inc.*, No. 2:11-cv-07178, Dkt. No. 102 (D.N.J. July 18, 2012).

Nevertheless, Actelion contends, without even attempting to address any of this opposing authority, that discovery prior to a ruling on its dispositive motion “would be an unnecessary waste of resources” because if the motion “is granted, this case will be over.” Actelion Br. 2. This argument, of course, could be made in *any* case where a party files a potentially dispositive motion.

Notably, Actelion does not even attempt to argue that its dispositive motion is likely to be granted, even though the probability of a dispositive motion to succeed is raised as a consideration in one of the cases relied on by Actelion. *See* Actelion Br. 2; *Victor v. Huber*, Civil No. 3:12-CV-282, 2012 WL 2564841, at *2 (M.D. Pa. July 2, 2012) (“[A] stay of discovery is appropriate pending resolution of a potentially dispositive motion where the motion ‘appear[s] to have substantial grounds’”) (citations omitted).² As courts in this District have

¹ As one commentator recently explained, the “general rule that discovery may proceed while motions to dismiss are pending has been underscored by numerous federal courts,” and the “mere filing of a case-dispositive motion, or the intent to file such a motion, does not constitute good cause.” Gideon Mark, *Federal Discovery Stays*, 45 U. Mich. J.L. Reform 405, 409-11 (Winter 2012). There are some “narrow exceptions” to this general rule, such as staying discovery pending a resolution of a defendant’s claim to qualified immunity or a defendant’s challenge to a plaintiff’s standing. *Id.* at 409 n.22; *e.g.*, *Harlow v. Fitzgerald*, 457 U.S. 800, 818 (1982) (qualified immunity); *United States Catholic Conf. v. Abortion Rights Mobilization, Inc.*, 487 U.S. 72, 79-80 (1988) (standing). However, none of these exceptions apply in this case.

² The other cases cited by Actelion that involve a motion to stay discovery pending a court’s ruling on a potentially dispositive motion are easily distinguishable. In *Mann v. Brenner*, 375 F. App’x 232, 239 (3d Cir. 2010), the court found, in conjunction with granting a discovery stay, that “none of [the plaintiff’s] claims entitle[d] him to relief” because he offered no facts to

held, it is Actelion's burden to demonstrate a "clear and unmistakable" likelihood of success on its potentially dispositive motion (and surely not Defendants/Counterplaintiffs' burden to show that the motion is likely to be denied). Ex. C, Order at 2, *Ariano Castro, M.D., P.A. v. Sanofi Pasteur Inc.*, No. 2:11-cv-07178, Dkt. No. 102 (D.N.J. July 18, 2012) (rejecting defendant's motion to stay discovery pending a ruling on cross-motions to dismiss because the court was "unable to find on the record before it that there [was] a 'clear and unmistakable result' that [it] could reach on the cross-motions"). For example, in *Gerald Chamales Corp.*, the defendants argued that their summary judgment motion had made a "strong showing" that the plaintiff's claim was "unmeritorious," but the magistrate judge was "unable to conclude that there [was] only one result that could be reached." 247 F.R.D. at 454. "In the absence of a clear and unmistakable result," the magistrate judge rejected the defendants' request for a discovery stay, explaining that the issuance of a stay should not "depend upon [a] prediction of how the District Judge will decide defendants' dispositive motion." *Id.* Unlike the moving party in *Gerald Chamales Corp.*, Actelion has not even attempted to make a "clear and unmistakable" showing that its dispositive motion is likely to be granted. Therefore, the Court should not consider the merits of Actelion's dispositive motion.

In any event, Actelion could not seriously argue that its dispositive motion is likely to be granted (and, therefore, provides the requisite good cause) for at least two reasons. First, in a case where the facts and law are most analogous to this one, the United States District Court for the Eastern District of Pennsylvania denied a similar motion to dismiss filed by the brand-name

support his claims but instead argued that he needed discovery to obtain such facts. Moreover, in *Weisman v. Mediq, Inc.*, Civ. A. No. 95-1831, 1995 WL 273678, at *2 (E.D. Pa. May 3, 1995), the court, in granting a discovery stay, stated that it would rule on the defendants' motion to dismiss "in the near future," such that the plaintiff was not "prejudiced by a stay in any significant way."

manufacturer. See Ex. D, Order, *Lannett Company, Inc. v. Celgene Corp.*, No. 2:08-cv-03920, Dkt. No. 197 (E.D. Pa. Mar. 31, 2011); Br. of Def. 2, *Lannett Co.*, No. 2:08-cv-03920, Dkt. No. 29-5 (E.D. Pa. May 28, 2010) (arguing that “no company, even a monopolist, should be forced to deal with its competitors”). Second, as Defendants/Counterplaintiffs’ forthcoming opposition to Actelion’s dispositive motion will make clear, Actelion cannot satisfy its burden to show that its “right to refuse to deal with its competitors” defeats Defendants/Counterplaintiffs’ antitrust claims under Section 2 of the Sherman Act and Section 56:9-4 of the New Jersey Antitrust Act, or Defendants/Counterplaintiffs’ state law claims for tortious interference.

II. ACTELION HAS NOT DEMONSTRATED THAT DISCOVERY IN THIS CASE WOULD BE UNDULY BURDENSOME OR EXPENSIVE.

To demonstrate good cause, Actelion must show that conducting discovery while its potentially dispositive motion is pending “‘will cause a defined and serious injury’ by pointing to ‘substantiated specific examples.’” *Worldcom Techs., Inc.*, 2002 WL 1971256, at *6 (citation omitted). In other words, “[b]road allegations of harm, unsubstantiated by specific examples or articulated reasoning,” are not sufficient. *Cipollone v. Liggett Grp., Inc.*, 785 F.2d 1108, 1121 (3d Cir. 1986) (citations omitted).

By contending that discovery in antitrust cases “can be extremely expensive” without providing any examples specific to this case, Actelion has not made the required showing.³ For

³ Actelion cites *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 558-59 (2007), for the proposition that discovery in antitrust cases can be extremely expensive. However, *Twombly* is distinguishable on its facts because it involved large class actions where the costs of discovery could have been used as leverage to force a settlement. *Id.* at 559 (“That potential expense is obvious enough in the present case: plaintiffs represent a putative class of at least 90 percent of all subscribers to local telephone or high-speed Internet service in the continental United States, in an action against America’s largest telecommunications firms (with many thousands of employees generating reams and gigabytes of business records) for unspecified (if any) instances of antitrust violations that allegedly occurred over a period of seven years.”). This case, on the other hand, is a business-to-business dispute, not a class action, and Defendants/Counterplaintiffs are seeking declaratory and injunctive relief in addition to monetary damages.

example, in *Gerald Chamales Corp.*, the defendants argued that “substantial time and money” would be spent on “preparation for and taking of depositions of defendants, in areas that may or may not be relevant to this case,” but the magistrate judge held that, “without any supporting evidence,” such “broad contentions” were insufficient to show good cause. 247 F.R.D. at 455 (citation omitted). Likewise, in *Worldcom*, the defendants’ argument that the requested discovery was “overly burdensome and would “cause unnecessary delay” without providing any specifics “other than to list examples of the discovery requests that they claim[ed] to be unreasonable” was insufficient to demonstrate good cause. 2002 WL 1971256, at *6. Accordingly, Actelion has failed to demonstrate that the proposed discovery will be unduly burdensome or expensive.

Moreover, Actelion would be on particularly weak footing in even attempting to argue that discovery in this case will be unduly burdensome where, as here, Defendants/Counterplaintiffs proposed a very reasonable discovery plan. Not only is the subject of the proposed discovery limited to the two Actelion products at issue, Tracleer and Zavesca, but Defendants/Counterplaintiffs also have offered to proceed with phased discovery that would defer more time-consuming and expensive discovery (*e.g.*, full-blown electronic document discovery and depositions) for three-to-four months, Ex. A, Joint Pre-Conference Report at Question No. 8(b) and (c), after which time the Court likely will have ruled on Actelion’s dispositive motion. The only discovery that would take place in the initial phase would be limited to written discovery and the exchange of core or “priority” documents.” *Id.* Although Actelion was aware of Defendants/Counterplaintiffs’ proposed discovery plan when it filed the pending Motion to Stay Discovery, it does not even mention the proposed plan except to note that Defendants/Counterplaintiffs proposed “to begin discovery immediately, albeit in phases.”

Actelion Br. 2. Clearly, Actelion cannot show that the proposed discovery will be unduly burdensome or expensive.

III. A STAY OF DISCOVERY WOULD PREJUDICE THE PUBLIC AND DEFENDANTS/COUNTERPLAINTIFFS BY PROLONGING THIS LITIGATION AND FURTHER DELAYING DEFENDANTS/COUNTERPLAINTIFFS' ABILITY TO BRING GENERIC VERSIONS OF TRACLEER AND ZAVESCA TO MARKET.

The public has a “particularly great” interest “in vigorously enforcing national anti-trust laws through the expeditious resolution of private antitrust litigation.” *In re Plastics Additives Antitrust Litig.*, 2004 WL 2743591, at *8 (citation omitted). Likewise, Defendants/Counterplaintiffs have a “right to have [their] case heard expeditiously while this lawsuit is pending.” *Gerald Chamales Corp.*, 247 F.R.D. at 455; *see also Forrest*, 757 F. Supp. 2d at 478 (“After plaintiff filed his lawsuit[,] he had a right to expect an expeditious resolution.”). A stay of discovery would prejudice both of these interests because if Actelion’s dispositive motion is denied (and Actelion has given the Court no reason to believe that it will be granted), then the stay will have prolonged this litigation by at least several months for no reason. Such additional, unjustified delay would be costly to Defendants/Counterplaintiffs and patients who use Tracleer and Zavesca. Defendants/Counterplaintiffs need to purchase samples of Tracleer and Zavesca in order to: (1) complete bioequivalence studies in support of their ANDAs; (2) obtain FDA approval of their ANDAs; and (3) bring their generic versions of Tracleer and Zavesca to market.

Put differently, this is not merely a case where if the court grants a discovery stay but ultimately denies Actelion’s dispositive motion, the stay will have resulted simply in a delay of retrospective monetary relief or fees. Instead, because Actelion’s patent on bosentan (the active ingredient in Tracleer) expires on November 20, 2015, the practical effect of delayed discovery is to further postpone resolution of whether Defendants/Counterplaintiffs are entitled to purchase

the samples to conduct bioequivalence studies. This, in turn, will enable Actelion to extend its monopoly *beyond patent expiry*, when generic entry should, at the very latest, occur. This additional delay will only serve to extend Actelion's monopoly, thereby forcing patients to continue paying high, monopolist prices for Tracleer and Zavesca and costing Defendants/Counterplaintiffs lost profits.⁴ Accordingly, a stay of discovery will severely prejudice both Defendants/Counterplaintiffs and patients.

CONCLUSION

For the foregoing reasons, Actelion's Motion to Stay Discovery should be denied, and discovery should commence immediately.

Date: February 5, 2013

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⁴ Another way of considering this is to acknowledge the disproportionate incentives and disincentives for delay. If Actelion's Motion to Stay Discovery is granted and its dispositive motion ultimately denied, then Actelion will have managed to further delay generic competition for two of its products, including Tracleer, the product responsible for the vast majority of its revenue and profits. In contrast, Defendants/Counterplaintiffs have no incentive to expend resources conducting discovery if they are likely to lose on a dispositive motion.

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CERTIFICATE OF SERVICE

I, A. Richard Feldman, hereby certify that, on February 5, 2013, I caused a true and correct copy of Defendants/Counterplaintiffs' Joint Memorandum in Opposition to Plaintiffs/Counterdefendants' Motion to Stay Discovery and proposed Order to be served via the Court's ECF System upon the following:

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